

EXHIBIT

31-b

requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims.

Comment 182: One comment argued that applicants would circumvent the proposed rules by designating a "picture claim" in all applications, thereby forcing the examiner to perform a complete search and examination, thus obviating any time or effort saved through the proposed changes.

Response: The Office has no objection to an applicant presenting a claim that recites in detail all of the features of an invention (*i.e.*, a "picture" claim) in an application. Nevertheless, the mere fact that a claim recites in detail all of the features of an invention is never, in itself, justification for the allowance of such a claim. See MPEP § 706.

Comment 183: One comment argued that according to *In re Wakefield*, 422 F.2d 897, 164 U.S.P.Q. 636 (C.C.P.A. 1970), applicant should be allowed to determine the necessary number and scope of claims.

Response: The changes adopted in this final rule do not set a *per se* limit on the number of claims that an applicant may file in an application. The applicant is free to file as many claims as necessary to adequately protect the invention. Applicant may present more than five independent claims or more than twenty-five total claims in an application if applicant files an examination support document before the first Office action on the merits of the application. The information provided by the applicant in the examination support document will assist the examiner in understanding the claimed invention, determining the effective filing date of each claim and the claim interpretation before the prior art search, understanding the state of the art and is most closely related prior art cited by the applicant, and determining the patentability of the claims. Thus, the examiner will be able to perform a better examination on the claims.

Comment 184: A number of comments argued that the rules would lessen the applicant's ability to file applications due to budget constraints and would increase costs for counseling applicants to get the best patent protection. One comment argued that the rules will increase applicant's costs such an extent that individual inventors and small companies will not be able to afford patent protection. Furthermore, the costs to comply with the rules will cause many people with technology that can spur innovation to be frozen out of the patent process.

Response: The current rules will only impact those applications that are filed with more than five independent claims or more than twenty-five total claims. If applicant presents more than five independent claims or more than twenty-five total claims, then applicant will be required to submit an examination support document under § 1.265. If an application is so significant that the applicant must present more than five independent claims or more than twenty-five total claims, then the additional costs should not be a deterrent.

Comment 185: One comment suggested that if the Office were to follow *Muncie Gear Works v. Outboard Marine & Mfg Co.*, late claiming of applications would likely decrease.

Response: In *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981), the Court of Customs and Patent Appeals discredited the idea that *Muncie Gear Works v. Outboard Marine & Mfg. Co.*, 315 U.S. 759 (1942) should be read as announcing a new "late claiming" doctrine. Rather, the Court of Customs and Patent Appeals interpreted the *Muncie Gear Works* holding of invalidity as grounded in the statutory prohibition against new matter.

Comment 186: A number of comments suggested that claims written in alternative form should not be treated differently from other claims, and that the Office should use election of species practice to identify alternatives to be used as representative claims. Several comments stated that claims drafted using Markush or other alternative language should be treated as single claims rather than treating each alternative as a separate claim. One comment stated that if members of Markush groups are counted separately, biotechnology and chemical applicants will file more multiple parallel applications. One comment requested clarification as to whether each element of a Markush claim would be considered to be an independent claim. One comment stated that Markush claims are beneficial to both the Office and applicants, and stated that the proposed changes would unfairly disadvantage members of the pharmaceutical community. One comment suggested that encouraging applicants to adhere more closely to existing 35 U.S.C. 112, ¶ 1 and 35 U.S.C. 101 requirements is a better means of managing the breadth of Markush claims than individualized claim counting schemes and required showings. One comment suggested that the Office should treat a Markush claim as a broad or generic claim. One comment asserted that the Office has

not provided any study or anecdotal evidence that identifies an abuse of Markush practice. One comment stated that the MPEP has never required that individual elements in a Markush group be treated separately, and that it is unfair to an applicant to use up claim designations on the individual elements of a Markush group because a reference teaching one element is applied to all.

Several comments argued that the proposed rule relating to determining the presence of separate claims in a Markush grouping will slow down prosecution, in part due to an increased number of petitions to review.

Response: The Office requested comments on how claims written in the alternative form, such as claims in an alternative form permitted by *Ex parte Markush*, 1925 Dec. Comm'r Pat. 128 (1924), should be counted for purposes of proposed § 1.75(b). See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 1302 Off. Gaz. Pat. Office at 1331. This final rule does not change the practice of the Office with regard to claims containing Markush or other alternative language. That is, a claim containing Markush or other alternative language would be considered as one claim for the purposes of determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b). However, the Office is evaluating changes to Markush practice, which could be implemented in a separate rule making.

The Office is also clarifying second action final practice with respect to using alternative language (*e.g.*, Markush claims). MPEP § 803.02 indicates that if an applicant amends a rejected Markush claim to exclude species anticipated or rendered obvious by the prior art, a second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed under § 1.97(c) with the fee set forth in § 1.17(p). MPEP § 803.02 provides this instruction in the context of the situation in which the examiner has determined that the Markush claim encompasses at least two independent or distinct inventions, has required applicant to make a provisional election of a single species, and has rejected the Markush claim on prior art grounds. This has led to some confusion as to when a second action on the rejected claims can be made final when the examiner has not found that the claim encompasses at least two independent